

## **REMARKS/ARGUMENTS**

### **I. Amendment to the Claims**

Claim 14 has been amended to clarify Applicants' claimed invention and incorporate the limitation of Claim 15. Support for the amendment can be found in Scheme 1 on page 5 of the Specification. No new matter has been added. Claim 15 has been cancelled without waiver or prejudice. Upon entry of the present amendment, Claims 14 and 16-23 will be pending.

### **II. Rejection Under 35 U.S.C 112, First Paragraph**

Claims 14 –23 are rejected under 35 U.S.C. 112, first paragraph because the Specification while being enabling for radiolabeled product containing  $^{18}\text{F}$ ,  $^{11}\text{C}$ ,  $^{131}\text{I}$ ,  $^{132}\text{I}$ ,  $^{124}\text{I}$ ,  $^{122}\text{I}$ , or  $^{125}\text{I}$ , does not reasonably provide enablement for all radiolabeled products. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully disagree and traverse this rejection.

As amended, Applicants' claimed invention is directed a purification process of a reaction mixture containing a radiolabelled product of Formula (III). The claimed invention comprises the steps of:

- (i) reacting a precursor of Formula (I) with a radioisotope or radiolabelling agent to form a solution-phase radiosynthesis reaction mixture comprising:
  - (a) the radiolabelled product of Formula (III), and
  - (b) excess precursor of Formula (I)
- (ii) contacting said solution-phase radiosynthesis reaction mixture with a solid-support bound scavenger group of Formula (IV) such that (b) forms a covalent bond with the scavenger group of Formula (IV); and
- (iii) separating the unbound radiolabelled product (a).

As would be understood by one of skill in the art, the radiolabelled product can be any radiolabelled product of Formula (III) that will not bind to the solid-support scavenger group of Formula (IV). The numerous examples of possible radiolabelled products that are given on pages 2-3 of the Specification as well as the Examples set forth on pages 18-20 not

only (i) provide enablement for the radiolabelled product of Formula (III) but would also (ii) enable one of skill in the art to make and use the claimed invention commensurate in scope with the claims and without undue experimentation. The claims satisfy the requirements of 35 U.S.C., first paragraph. Applicants respectfully request this rejection be withdrawn.

### **III. Rejection Under 35 U.S.C 112, Second Paragraph**

Claims 14 –23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. This rejection has, in part, been rendered moot by the present amendment to the claims and, in part, respectfully traversed.

(a) Claims 14-23 are ambiguous because it is unclear what reaction by products are being referred to in the claim. This rejection has been rendered moot by the present amendment to claim 14. Applicants respectfully request this rejection to be withdrawn.

(b) Claims 14-23 are ambiguous because it is unclear what radiolabeled products, excluding products labeled with  $^{18}\text{F}$ ,  $^{11}\text{C}$ ,  $^{131}\text{I}$ ,  $^{132}\text{I}$ ,  $^{124}\text{I}$ ,  $^{122}\text{I}$ , or  $^{125}\text{I}$ , are compatible with the invention. Applicants respectfully disagree and traverse this rejection. As would be understood by one of the skill in the art the radiolabel R\* of the radiolabeled product will be any radiolabel or radiolabeled moiety capable of reacting the precursor of Formula (I) (Specification, page 4, lns. 6-8 and Scheme 1 on page 5). The metes and bounds of the claims would be understood by one of skill in the art. Applicants respectfully request this rejection be withdrawn.

### **IV. Conclusion**

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Appl. No. 10/560,508  
Amdt. Dated February 28, 2011  
Reply to Office action of September 30, 2010

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.16(j) or 37 CFR 1.136(a) which may be required, or credit any overpayment, to Deposit Account No. 502-665 in the name of GE Healthcare, Inc.

Respectfully submitted,

/Christine Lee/  
Christine Lee  
Reg. No. 42,788  
Attorney for Applicants

GE Healthcare, Inc.  
101 Carnegie Center  
Princeton, NJ 08540  
Phone (609) 514-6418  
I:\IP\Response to Office Action\PH\PH0423 (FINAL).doc